

Environmental Protection Agency

§ 177.1

the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 177—ISSUANCE OF FOOD ADDITIVE REGULATIONS

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AUTHORITY: 21 U.S.C. 348, 371(a) 331(j); Reorg. Plan No. 3 of 1970.

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Subpart A—General Provisions

§ 177.1 Scope and applicability.

(a) This part establishes procedures for the establishment, modification, or revocation by the Administrator of food additive regulations under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348, for food additives which may result in pesticide residues in or on processed food or otherwise affect the characteristics of such food.

(b) Part 178 of this chapter contains procedures for filing objections and requests for hearings under FFDCA section 409(f) on food additive regulations or petition denials issued under this part. Part 179 of this chapter contains rules governing formal evidentiary hearings under FFDCA section 409(f).

(c) Part 180 of this chapter contains regulations establishing tolerances, or exemptions from the necessity for a tolerance, for pesticide residues on raw agricultural commodities under FFDCA section 408. If the use of a pesticide chemical in the production, storage, or transportation of a raw agricultural commodity (RAC) in conformity with such a tolerance or exemption results in the presence of a pesticide residue in or on processed food made from the RAC, FFDCA section 402(a)(2)(C) provides that such pesticide residue shall not be deemed unsafe for the purposes of FFDCA section 409 (despite the absence of a food additive regulation regarding such residue on the processed food) if the residue in or on the RAC has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the RAC. However, a food additive regulation would be required if the level of the pesticide residue in the processed food when ready to eat exceeded the level permitted in the “parent” RAC by the tolerance established under FFDCA section 408. In addition, if a pesticide residue in or on a processed food results from the application of a pesticide during or after processing, the food would be unsafe